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JUN 2 3 2000

VARIAN
medical systems

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Premarket Notification [510K] Summary as required by 21 CFR 807.92

Date Summary was prepared;
May 22, 2000

Submitter's Name:
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Device Name:
VARiS 1.4g

Classification Name:
Medical Charged Particle Radiation Therapy Systems

Predicate Device:
Varian Origami, Version 1.0, K935201

Product Description:

VARiS 1.4g is an information system designed to assist a Clinic in managing an Oncology practice. VARiS 1.4g is composed of several applications. The basic applications are VARiS Clinic and VARiS Treatment. Optional applications include VARiS Simulation, VARiS Reports, VARiS Schedule, and VARiS Charges. Connectivity with external applications may be accomplished using the optional VARiS Link module.

The VARiS 1.4g Clinic application provides the foundation for the VARiS information system. It includes the tools necessary to manage the radiotherapy department's clinical and business information. It includes Patient Registration, used to enter and review patient demographic data; Patient Chart, used to enter and review patient radiotherapy clinical data; Mini-Schedule, used to schedule patient appointments on treatment and simulation machines for single & multiple days; Patient Check-In, used to indicate patient arrival for scheduled appointments; and Administration, used to handle system administration tasks.

The VARiS 1.4g Treatment application provides a Record & Verify function designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring set up parameters and preventing the radiation therapy device from commencing irradiation while any parameter is out of conformance with the treatment plan. It also provides for selecting patients from a queue provided by the schedule, retrieval of plans for the selected patient, evaluation of selected treatment plan to determine whether predefined dose limits will be exceeded, auto sequencing of fields for the selected patient, acquisition of positional data from radiation therapy devices, and overriding of treatment parameters based on user rights. It also records results of treatment delivery, including dose delivered to defined anatomical sites.

The optional VARiS 1.4g Simulation application provides an interface to radiation therapy simulation devices. It allows for selecting patients from a queue provided by the schedule, monitoring radiation therapy simulation device setup parameters and acquisition of these setup parameters. It also enables the operator to create and modify simulation and treatment fields, and to associate simulation fields with a patient's chart record.

The optional VARiS 1.4g Reports application provides predefined reports, viewed online or printed, covering a variety of topics useful in managing an Oncology practice. It also provides a report builder to allow a user to generate custom reports.

The optional VARiS 1.4g Schedule application is a resource manager for oncologists, staff, machines and all other oncology-related activities. It provides daily and monthly scheduling views, editing of these views, simple rescheduling of all resources related to an appointment, and patient & staff tracking by scheduled activity.

It allows automatic scheduling of full courses of treatment, conflict resolution, task assignment, status and duration tracking for all activities.

The optional VARiS 1.4g Charges application provides treatment-strategy templates to forecast and track treatment and administrative activities, posting of charges for completed activities, review of costs by categories, review using online screens and printed reports, and cost & charge export via Link.

The optional VARiS 1.4g Link module provides an interface that allows a user to insert, retrieve and update data in VARiS database while maintaining data integrity, using SQL programming principles.

VARiS 1.4g is designed to run on PC servers running Microsoft® Windows NT Server; and PC client workstations running 95, Windows 98 or Windows NT Workstation. The VARiS 1.4g system runs on a Sybase version 11.0.2 database, and is accessed using Sybase Open Client version 10.0.4.

Intended Use:

The VARiS RV function is designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring set up parameters and preventing the radiation therapy device from commencing irradiation while any parameter is out of conformance with the treatment plan. Additional applications provide various data management and library functions.

Technological Characteristics:

VARiS 1.4g is an information system designed to assist a Clinic in managing an Oncology practice. It is a client-server system. VARiS 1.4g is designed to run on PC servers running Microsoft® Windows NT Server; and PC client workstations running Windows 95, Windows 98 or Windows NT Workstation. The VARiS 1.4g system uses a Sybase version 11.0.2 database, and is accessed using Sybase Open Client version 10.0.4. The applications programs are written in Gupta SQL Windows and Microsoft Visual C++. Network communication protocol is TCP/IP.

For details of features, see the attached "Specification Comparison Chart", Tab F.

VARiS 1.4g & Origami Features/Specifications Comparison Chart

Origami	VARiS 1.4g
Intended Use: The VARIS RV Application is designed to assist the Radiation Oncologist in providing accurate treatment set ups for each patient by monitoring set up parameters and preventing the CLINAC radiation therapy linear accelerator from commencing irradiation while any parameter is out of conformance with the treatment plan. Additional applications provide various data management and library functions.	**Intended Use:** The VARIS RV function is designed to assist the operator of a radiation therapy device in providing accurate treatment set ups for each patient by monitoring set up parameters and preventing the radiation therapy device from commencing irradiation while any parameter is out of conformance with the treatment plan. Additional applications provide various data management and library functions.
VARiS Clinic: VARiS Clinic provides the foundation for the VARiS system. It includes the tools necessary to manage the radiotherapy department's clinical and business information. It includes the following applications: Patient Registration – used to enter and review patient demographic data, including: • Patient address, permanent & local • Referring and associated physicians • Emergency contacts • Employer information Patient Chart – used to enter and review patient radiotherapy clinical data. Provides the following capabilities: • Record primary & secondary diagnoses for patients • Record courses for patient treatment including prescription information • Record sites for dose tracking purposes • Track dose information • Shaper integration to define & review plans with MLC fields Schedule functionality identified: Schedule patient appointments on treatment and simulation machines for single & multiple days Patient Check-In – used to indicate patient arrival for scheduled appointments Administration – used to handle system administration tasks. Provides the following capabilities: • Delete patients • Provide routine server backup of patients and database • Define treatment machine configurations • Define physician & staff profiles • Assign logins and user rights	**VARiS Clinic:** VARiS Clinic provides the foundation for the VARiS system. It includes the tools necessary to manage the radiotherapy department's clinical and business information. It includes the following applications: Patient Registration – used to enter and review patient demographic data, including: • Patient address, permanent & local • Referring and associated physicians • Emergency contacts • Employer information Patient Chart – used to enter and review patient radiotherapy clinical data. Provides the following capabilities: • Record primary & secondary diagnoses for patients • Record courses for patient treatment including prescription information • Record anatomical sites for dose tracking purposes • Track dose information • Shaper integration to define & review plans with MLC fields Mini-Schedule – used to schedule patient appointments on treatment and simulation machines for single & multiple days Patient Check-In – used to indicate patient arrival for scheduled appointments Administration – used to handle system administration tasks. Provides the following capabilities: • Delete patients • Provide routine server backup of patients and database • Define treatment machine configurations • Define physician & staff profiles • Assign logins and user rights
VARiS Treatment: VARiS Treatment provides the following capabilities: • Patient selection from a queue provided by the schedule • Retrieval of plans for the selected patient • Evaluation of selected treatment plan to determine whether predefined dose limits will be exceeded • Auto sequencing of fields for the selected patient • Interface to Clinac radiotherapy machines • Acquisition of positional data from the Clinac • Verification that the Clinac is set up properly and prevention of beam if Clinac setup does not match the plan	**VARiS Treatment:** VARiS Treatment provides the following capabilities: • Patient selection from a queue provided by the schedule • Retrieval of plans for the selected patient • Evaluation of selected treatment plan to determine whether predefined dose limits will be exceeded • Auto sequencing of fields for the selected patient • Interface to Clinac radiotherapy machines • Acquisition of positional data from the Clinac • Verification that the Clinac is set up properly and prevention of beam if Clinac setup does not match the plan

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VARiS 1.4g & Origami Features/Specifications Comparison Chart

Origami	VARiS 1.4g
• Patient and field information transfer to MLC for setup and verification for both static and dynamic MLC fields • Override treatment parameters based on user rights • Record results of treatment delivery, including dose delivered to defined sites	• Patient and field information transfer to MLC for setup and verification for both static and dynamic MLC fields • Override treatment parameters based on user rights • Record results of treatment delivery, including dose delivered to defined sites ***New in VARiS 1.4g:*** • Extensible Verification Interface (EVI) provides connectivity to non-Varian radiation therapy devices • VARiS Treatment displays & verifies parameters particular to non-Varian radiation therapy devices
VARiS Reports: VARiS Reports provides the following: • Predefined reports, viewed online or printed, covering a variety of topics • A report builder to allow a user to generate custom reports	**VARiS Reports:** VARiS Reports provides the following: • Predefined reports, viewed online or printed, covering a variety of topics • A report builder to allow a user to generate custom reports
Schedule: Functionality identified in Origami: • Daily, weekly and monthly scheduling views & edit • Simple rescheduling of all resources related to an appointment • Patient & staff tracking by scheduled activity	**VARiS Schedule:** VARiS Schedule is a resource manager for oncologists, staff, machines and all other oncology-related activities. It provides • Daily and monthly scheduling views & edit • Simple rescheduling of all resources related to an appointment • Patient & staff tracking by scheduled activity ***New in VARiS 1.4g:*** • Automatic scheduling of full course of treatment • Scheduling conflict resolution • Task assignment to individuals and groups • Status & duration tracking for all activities
Simulation: Functionality identified in Origami: • Acquire field parameters from a Simulator	**VARiS Simulation:** VARiS Simulation provides the following capabilities: • Acquire field parameters from a Simulator ***New in VARiS 1.4g:*** • Select patient from a queue provided by the schedule • Create & modify simulation and treatment fields • Associate simulation fields with a patient's chart record
Archive: Functionality identified in Origami: Provides archive & restore of patient data sets	Archive: This feature is not available in VARiS 1.4g
Database: The VARiS database is run on Sybase version 4.9.2, and is accessed using Sybase Open Client version 4.9.	**Database:** The VARiS database is run on Sybase version 11.0.2, and is accessed using Sybase Open Client version 10.0.4.
Network Configuration: VARiS is designed to run on PC servers running Novell Netware 3.1x; and PC client workstations running Microsoft® Windows for Workgroups 3.11.	**Network Configuration:** VARiS is designed to run on PC servers running Microsoft® Windows NT Server; and PC client workstations running 95, Windows 98 or Windows NT Workstation.
	New in VARiS 1.4g: **VARiS Link** VARiS Link is an interface that allows a user to insert, retrieve and update data in VARiS database while maintaining data integrity, using SQL programming principles.

VARiS 1.4g & Origami Features/Specifications Comparison Chart

Origami	VARiS 1.4g
	New in VARiS 1.4g: **VARiS Charges** VARiS Charges provides the following capabilities: • Treatment-strategy templates to forecast and track treatment and administrative activities • Posting of charges for completed activities • Review of costs by categories • Review using online screens and printed reports • Cost & charge export via Link

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2000

Linda Nash
Corporate Director, Regulatory Affairs
and Quality Assurance
Varian Medical Systems
3100 Hansen Way M/S H-055
Palo Alto, CA 94304-1129

Re: K001643
VARiS 1.4g (Medical Charged Particle Radiation Therapy System, Record and Verify System)
Dated: May 22, 2000
Received: May 30, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Nash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

VARIAN
medical systems

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Indications For Use

510(k) Number: 001643

Device Name: VARiS 1.4g

Indications For Use:

VARiS is used as an ancillary (or adjunct) device to assist the Radiation Therapist in reducing inaccuracies in setting up treatments to be delivered by a radiation therapy device. The indications for use include any disease or condition treatable with radiation therapy, including but not limited to cancer.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001643